REMARKS

Election/Restriction

On September 13, 2006 the Examiner contacted the undersigned by telephone with a restriction requirement in the referenced application, where the restriction was between Group I, claims 1-17, and Group II, claims 18-61. The undersigned elected Group I, claims 1-17, with traverse. That election is confirmed here. The Examiner then withdrew Group II claims 18-61 from further consideration in the pending office action. Applicants request that the Examiner consider the basis for the traversal, withdraw the restriction requirement, and examine all 61 claims now pending.

The Examiner cites PCT Rules 13.1 and 13.3, and 37 CFR 1.475(d) in stating that Claims 18 to 61 do not relate to a single inventive concept, and emphasized that to relate to a single inventive concept compound, method and composition claims must be of the **same scope**. Applicants have reviewed these provisions and the word "scope" does not appear anywhere. Thus the Examiner appears to be applying a standard not found in the relevant rules.

The rules do require that there be "a technical relationship among those inventions involving one or more of the same or corresponding special technical features". Special technical features must "define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art". Here, the special technical feature of all of claims 1-61 is a particular set of novel and non-obvious CGRP modulators. That is, compound claims 1-14, composition claim 15, *method of use claims 18-39, and composition claims 40-61, all share the very same technical feature: the claim 1 novel and non-obvious CGRP modulators.* The recitation in claims 18-61 of additional components, such as additional active agents, does nothing to change this fact. (The Examiner's position seemingly stems from the idea that claims 18-61 are combinations of known elements and therefore must be examined with an eye towards synergistic properties. This is not the case here since all claims relate to new and non-obvious compounds.)

Moreover, even if "scope" were the relevant issue, claims 18-61 are of a much narrower scope than claims 1-17 since the presence of an additional feature is required in claims 18-61. Many more compositions are included within claim 15 (inert carrier plus the compound of Claim 1) than are included within claim 40 (agent selected from serotonin agonists, analgesics,

anti-inflamatory agents, and anticonvulsants plus the compound of claim 1). It makes no sense, from the standpoint of Examiner search effort, to examine the broader claims while restricting out narrower ones.

In view of the above, it is respectfully requested that the restriction requirement be reconsidered and claims 18-61 be examined in this application.

Claim Rejections – 35 USC §112

Claims 1-22 stand rejected under 35 U.S.C. 112 as allegedly being indefinite. Specifically, the Examiner takes the position that the claim terms "heteroaryl" and "heterocycle" are indefinite because it is not known, for instance, how many and which atoms are present, and/or how many rings are present. Applicants respectfully traverse.

Applicants direct the Examiner to the specification at page 16, lines 4 through 32, wherein complete definitions for both "heteroaryl" and "heterocycle" are provided. One skilled in the art would recognize and understand that the terms "heteroaryl" and "heterocycle" in the claims are limited by these definitions. Moreover, Applicants believe that any attempt to include in the claims all of the limitations found in the specification at page 16, lines 4 through 32, would result in a cumbersome claim language.

Claims 1-17 stand rejected under 35 U.S.C. 112 as allegedly being indefinite for reciting "and" before "pharmaceutically acceptable salts and individual diastereomers thereof." The claims have been amended to read "or a pharmaceutically acceptable salt or an individual diastereomer thereof".

Claim 16 stands rejected under 35 U.S.C. 112 as allegedly failing to meet the enablement requirement. Applicants traverse. Claim 16 relates to a method for antagonizing CGRP receptors by administering a compound described by claim 1. The specification provides ample instructions for making the claim 1 compounds, including 57 synthetic examples, and the synthesis of compounds not specifically exemplified is well within the abilities of one skilled in the art. Administering the claim 1 compound to a patient is also well within the abilities of one skilled in the art, particularly in view of extensive guidance regarding dosage forms and dosage amounts on pages 24-27 of the specification. Finally, the skilled artisan would recognize that the claim 1 compounds have CGRP antagonistic activity in view of the assays described on pages 19-21 of the specification, and the results thereof, i.e., that all exemplary compounds were found to have K_i or IC_{50} values of less than about 50 μM. (The assays described in the specification may be routinely employed to select appropriately selective and active compounds and to eliminate other compounds.) Thus, all

features of claim 16 (how to make the compound, how to administer the compound, and how to select the compound to be administered), and claim 16 as a whole, are enabled.

The Examiner's focus on "benefit" to be gained by administering a CGRP antagonist is misplaced. "Benefit" relates to usefulness and utility, which are not enablement issues. Moreover, the background section of the instant application details the many ways that CGRP antagonism plays a role in a variety of conditions and diseases. The benefits of antagonizing CGRP receptors, either in treating or studying the noted conditions and diseases (if the issue of "benefit" was even relevant), is apparent.

Claim 17 similarly stands rejected under 35 U.S.C. 112 as allegedly failing to meet the enablement requirement. Applicants again traverse. Claim 17 relates to treatment of migraine and cluster headaches using a claim 1 compound. As noted above, the specification provides ample instructions for making and administering claim 1 compounds. The disclosed assays provide a simple means for determining if a compound is an active CGRP antagonist, and the correlation between migraine / cluster headaches and CGRP receptors *is* recognized in the art, as detailed extensively on pages 1-2 of the specification.

Moreover, there is no "large degree of experimentation", and in any event it is established law that even extensive experimentation is not "undue" if such experimentation is routine in the field. The Examiner has recognized that the practitioner of claim 17 is an experienced physician who doubtless could perform any routine experimentation and/or optimization required.

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In view of the amendments and remarks presented above, Applicants respectfully request that any objections and rejections of claims be withdrawn and a Notice of Allowance be promptly issued.

Respectfully submitted,

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